Silmax implants

K002629

NOV 2 0 2000

Enclosure I

510(k) Summary

Trade Name
Silmax Contour Carving Block Implant

Common Name
Silicone Contour Carving Block Implant

Substantial Equivalence
The Silmax Contour Carving Block Implants will be equivalent to: K973728 Silicone Carving Block by Hanson Medical, Inc.; K981851 Silicone Carving Block by Silimed, Inc.; and K982688 Spectrum Designs Pre-Form Contour Silicon Carving Block.

Material Safety
The silicone materials used to make Silmax Contour Carving Block Implant are routinely tested for Appearance, Durometer, and Cytotoxicity. MSDS information is available from the manufacturer. Materials used in Silmax Pectoral Implants are FDA master-filed materials from Nusil Technologies, Inc's, healthcare, implantable-grade, silicones (MAF-612.)

Device Description
For over 10 years, silicone prosthetic implants have been hand-carved by surgeons from blocks of silicone, where a pre-shaped, cut-to-fit implant is desired. The carved implant is shaped by the surgeon using a scalpel or surgical scissors prior to the surgery, in order to add prominence or projection to submuscular or subdermal deficiencies, whether congenital or acquired by trauma or disease. The pre-formed or curved block allows the surgeon easier access to smooth tapering when difficult-to-carve sections of the block exist due to low durometer (soft) block material. The Silmax Coutour Carving Blocks Implants will be made available in seven (7) shapes with varying sizes from 6.5cm x 14.5cm x 1.0cm to 14cm x 14cm x 4cm.

Indications for use
Silmax Contour Carving Block Implants are indicated for use in patients who require aesthetic, corrective or reconstructive surgery. The appropriate size of the implant will be determined prior to surgery by an examination of the patient requiring the surgery. Measurements of pre-existing tissue should be noted so that there will be adequate tissue covering the implant.

Contraindications
Silmax Contour Carving Block Implants are contraindicated for use if there are any of the following: Insufficient tissue covering or unusual skin or muscle atrophy. Any pre-existing patient drug use, conditions or diseases, which put the patient at higher, risk during implant surgery. Any condition or diseases that compromises the surgeon's ability to create a large enough pocket to insert the implant and avoid explant surgery.

Clinical Tests: None
Longitudinal Tests: None
Adverse Safety and Efficacy Tests: None

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2000

Mr. Rob Fritzenkotter
Pillar Surgical, Inc.
P.O. Box 8141
La Jolla, California 92038-8141

Re: K002629
Trade Name: Silmax Contour Carving Block
Regulatory Class: II
Product Code: JOF
Dated: August 18, 2000
Received: August 23, 2000

Dear Mr. Fritzenkotter :

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Milhauser

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002629

510(k) NUMBER (IF KNOWN): K002629

DEVICE NAME: SILMAX CONTOUR CARVING BLOCK

INDICATIONS FOR USE:

Indications for use:

Silmax Contour Carving Block Implants are indicated for use in patients who require aesthetic, corrective or reconstructive surgery to correct sub dermal or muscular defects. The appropriate size of the implant will be determined prior to surgery by an examination of the patient requiring the surgery. Measurements of pre-existing tissue should be noted so that there will be adequate tissue covering the implant.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-

for Mark N Milhern

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002629